**ADVAMED RESPONSE TO THE DEPARTMENT OF COMMERCE INTERATIONAL TRADE ADMINISTRATION REQUEST FOR COMMENTS ON PRIORITIES FOR THE TRANSATLANTIC INNOVATION DIALOGUE**

## Introduction

The Advanced Medical Technology Association (AdvaMed) welcomes the opportunity to provide comments on the priorities for the Transatlantic Innovation Dialogue as requested by Federal Register notice Vol. 74, No. 250. Trans Atlantic trade is vitally important to our member companies, and is our largest trading area, valued at over $55 billion in 2008. The United States (US) and Europe Union (EU) are the world's leading developers, producers and consumers of medical technology. The medical technology sector directly employs well over 357,000 people in the United States and 529,000 people across Europe. The economic impact of this sector is strong as each medical technology job generates an additional 4.5 jobs.

AdvaMed's 1,600 members produce the medical devices, diagnostic products and health information systems that are transforming health care. Our members range from the largest corporations to the smallest innovators. Eighty percent of our members are small and medium enterprises (SMEs). Our members produce nearly 90 percent of the health care technology purchased annually in the US and more than 50 percent purchased globally.

## Mutually Beneficial Areas of Cooperation

There is great potential in this Transatlantic Innovation Dialogue bringing together interdisciplinary policy discussions as often policy development remains in specific agencies that have little awareness of how their policy or regulations impact innovation and entrepreneurial activities. AdvaMed would like to propose the following three areas for work:

### E-Health Systems

Both the US and the EU have strong interests and initiatives currently in progress in the development of e-Health systems and in particular the sharing of Electronic Health Records (EHR) between healthcare information technology (IT) systems. This is evidenced by:

- The recent US "American Recovery and Reinvestment Act" (ARRA) which has set aside $32 billion for physicians and hospitals to adopt use of interoperable EHR software. In the US, standards harmonization is performed by both global private initiatives such as Integrating the Healthcare Enterprise (IHE) and Continua, as well as by federally driven stakeholder consensus such as the Healthcare Information Technology Standards Panel (HITSP) and the ARRA HIT Standards Federal Advisory Committee.

- The EU Health Records interoperability is equally high on the European agenda driven by the Directive on patients' rights to cross-border healthcare and the Recommendation on cross-border interoperability of electronic health record systems. Europe is organizing its intra-European standards harmonization in collaboration with the same global private initiatives such as IHE and Continua in the European Commission sponsored eHealth INTEROP Standards Mandate and cross-country pilot projects for the exchange of records (epSOS).

By providing efficient management and flow of patient records, health care costs will be reduced by eliminating unnecessary tests or treatment. EHR will enhance patient safety by reducing mistakes as they more accurately record doctor's orders and treatments. The goal is better treatment and healthier patients which ultimately will result in a long-term cost savings for the system as a whole. An important aspect to the global success of EHRs will be systems' interoperability and compatibility. By collaboratively developing EHR software to mutually recognized international interoperability standards, the US and EU will facilitate the speed with which EHR systems become available and, most importantly, the overall safety, quality, and reliability of EHR products.

***Suggested activity:*** The goal of the US and the EU having mutually recognized interoperability standards is a pragmatic and achievable one given the consistency of standards selections made to date. A Transatlantic Innovation Dialogue coordination effort would ensure a faster convergence and avoid inefficiencies and discrepancies. It would be most useful to have this effort organized to involve stakeholders such as the private global initiatives (i.e. IHE, Continua) on interoperability standards for eHealth and the US (HITSP) and EU (eHealthINTEROP) governmental initiatives.

**E-Labeling**

The medical technology sector is known for rapid innovation. On average, medical devices are improved or changed every 18 months. It is very important that health care providers are kept fully informed of Instructions for Use (IFU) for medical devices to ensure appropriate use and safety for the patient. The electronic substitution of traditional paper product labeling, IFU (such as package insert, directions for use, etc.), has proved beneficial to the US health care industry. The benefits to health care practitioners, especially if the information is web-based, include:

- easier and faster access to information
- approved products to market faster
- quickly informed of any revisions of Instructions for Use
- greater volumes of information possible
- user-interactive features (audio, video – product demonstrations)
- central resource if hard copy information lost
- email updates (if customer opts in) to product alerts
- environmental benefits as there is less paper and packaging waste and more efficient use of inventory and transportation space.

It would be beneficial to both the industry and EU health care practitioners if e-labeling for medical devices was more fully explored and utilized. A very large volume of labeling is required to accommodate the 23 official EU languages – or the multiple languages where the product is sold if not distributed EU-wide.

***Suggested activity:*** Form a working group to explore why EU member states are not fully utilizing provisions in the Medical Device Directive and Active Implantable Medical Device Directive that allow for e-labeling of medical technologies and suggest solutions. Improved utilization would create efficiencies in receiving up-to-the minute information on products as well as provide environmental and cost savings benefits. The European Commission to more fully mandate e-labeling, perhaps as a regulation to allow for consistency across member states, of a wider range of medical technologies. Wide adoption of e-labeling in Europe could lead to tens of millions of dollars in savings annually for the industry, provide better information to health care practitioners as well as spare thousands of tons of paper that end up as waste.

**Innovation and Competiveness = Education**

Innovations in technology are driving the need for new skills and curricula. Sometimes the full potential of an innovation can not be utilized due to the lack of qualified, skilled professionals and the conservative, hesitant nature of existing professional practices. Healthcare is a key field for this type of discussion.

***Suggested activity:*** Align and identify relevant fields of innovation where the uptake and understanding of new innovations should be improved. Identify barriers to use and understanding as well as human resource issues – such as matching projected development of technologies to the need for scientists, engineers, health care providers.

**International Standards and Regulatory Recognition: ISO 13485**

Medical devices often are complex manufactured products that must meet stringent requirements for safety and performance. Often these requirements differ from market to market. Regulatory harmonization would improve the access of citizens to innovative medical technologies. For a manufacturer to ensure a high level of safety and performance of a medical device, it must implement careful controls and testing throughout the design, development, manufacturing, distribution and post-market surveillance process. For these reasons, regulators in the US and the EU, as well as the Global Harmonization Task Force (GHTF), take the approach of requiring manufacturers of medium and high-risk devices to be responsible for the safety and performance of their product through implementation of a quality management system as the foundation for regulatory control. European member states and most GHTF members utilize the international standard ISO 13485, *Medical devices – Quality management systems – requirements for regulatory purposes*, which is the well-established and recognized basis for these requirements. This quality management system covers the design and development process, the manufacturing process, inputs from suppliers, distribution, and post-market surveillance.

The United States is considering a proposal in the Asia Pacific Economic Cooperation (APEC) forum to harmonize regulatory requirements for medical technology products by 2020. This would facilitate trade in life-saving medical devices and promote innovation in this field region-wide. Such a move would be especially helpful to SMEs. With the goal of global regulatory harmonization, it would be useful for the Innovation Dialogue to incorporate this goal of harmonization of regulatory requirements for medical technology products by 2020.

***Suggested activity:*** Establish a goal of US-EU regulatory harmonization in medical technology by 2020 through use of ISO 13485. US regulators would more fully utilize inspections of medical device facilities performed by EU notified bodies that have successfully been certified to meet the requirements of the internationally accepted quality management systems standards ISO 13485.